

### **REMARKS/ARGUMENTS**

By the present amendment, claims 1 and 17 have been amended in order to specify that the chymosin is "biologically active" and that the grinding is in "water or a buffer". Support for the "biologically active" amendment can be found in Example 3, for example, on page 28, line 5 of the application as filed. Support for grinding the seed in "water or buffer" can be found on page 20, line 32 to page 21, line 1. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further continuation, continuation-in-part or divisional application. The amendment does not contain new matter and its entry is respectfully requested.

The Official Action dated September 27, 2006 has been carefully considered. It is believed that the amended claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **35 USC §103**

The Examiner has objected to claims 1, 3, 5-17 and 21-23 under 35 USC §103 as being unpatentable over Willmitzer et al. (WO 92/01042) in view of Kusnadi et al, 1998 (Biotech. Bioeng, Vol. 60, No. 1, p. 44-52) and Applicant's admitted prior art. We respectfully disagree with the Examiner for the reasons that follow.

Willmitzer et al. generally teaches that industrial enzymes, such as chymosin, can be prepared in plants. The present claims relate to the production and isolation of biologically active chymosin from plant seeds. Willmitzer et al. does not produce or isolate chymosin from plant seeds and does not teach how to isolate chymosin from plant seeds. Further, there is nothing in Willmitzer et al. that would motivate one of skill to develop an isolation method as described in the claims.

On page 4, paragraph 2 of the office action, the Examiner confirms that "Willmitzer et al. does not teach production of chymosin from transgenic seed by fractionating crushed transgenic plant seed into an oil fraction, an aqueous fraction and an insoluble fraction". Applicant agrees. However, Applicant disagrees that the deficiencies in Willmitzer are remedied by Kusnadi et al. Kusnadi et al. discloses the production of  $\beta$ -glucuronidase (rGUS) in transgenic corn seed. The Examiner notes that the hexane extraction method of Kusnadi et al. did not destroy the activity of the rGUS. However, Kusnadi et al. does not disclose the isolation of chymosin from plant seeds. Further, the method used in Kusnadi would not be useful in isolating biologically active chymosin.

As stated in the Declaration of Dr. David Dennis that we filed with the response on May 27, 2004, the "methodologies of protein purification have to be developed and established for each protein that is purified". In the office action, the Examiner states that the Declaration is unpersuasive as no "claims are drawn to 'active' or 'pure' chymosin". As noted above, independent claims 1 and 17 have now been amended in order to specify that the chymosin is biologically active. Therefore, the scope of the argument presented in the Dennis Declaration is in accordance with the scope of the claims.

Importantly, Applicant has used a hexane extraction method to isolate chymosin from plant seeds and have shown that hexane extraction destroys the biological activity of chymosin. In this regard, we enclose a Declaration under 37 C.F.R. §1.132 by Dr. Brent Pollock who is the Group Leader of Process Development at SemBioSys Genetics Inc., the assignee of the present application (hereinafter "the Declaration"). The results in the Declaration demonstrate that hexane extraction is not a useful method for isolating chymosin from seed.

It is also noted that Kusnadi et al. dry crushes the plant prior to hexane extraction of the protein. The results in the Declaration demonstrate that dry crushing of plant seeds containing chymosin destroys the biological activity of chymosin. The claims have been

amended to specify that the crushing of the seed occurs in the presence of water or a buffer. Therefore, the Kusnadi et al. reference is not applicable for isolating biologically active chymosin from seed.


In summary, Willmitzer et al. does not teach or suggest how to isolate and purify biologically active chymosin from plant seeds. At the time of the invention, no prior art, including Applicant's admitted prior art, taught or suggested how to isolate chymosin from seed. In fact, the state of the art at the time of the invention taught dry crushing and hexane extraction of protein from plant seeds as described in Kusnadi et al. The prior art method is clearly not applicable to chymosin (as evidenced by the attached Declaration) as the isolated chymosin would not be biologically active.

In view of the foregoing, we respectfully request that all of the objections to the claims under 35 U.S.C. §103 be withdrawn.

The Commissioner is hereby authorized to charge any deficiency in fees (including any claim fees) or credit any overpayment to our Deposit Account No. 02-2095.

In view of the foregoing, we submit that the application is in order for allowance and an early indication to that effect would be greatly appreciated.

Respectfully submitted,  
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